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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,004	02/08/2006	Francesca Ghigini	41622/AJ/CD	5829

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Modiano & Associati  
Via Meravigli 16  
Milano, 20123  
ITALY

06/10/2009

EXAMINER
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JANG, CHRISTIAN YONGKYUN

ART UNIT	PAPER NUMBER
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3735

MAIL DATE	DELIVERY MODE
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06/10/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/568,004	<b>Applicant(s)</b> GHIGINI, FRANCESCA	
	<b>Examiner</b> CHRISTIAN Y. JANG	<b>Art Unit</b> 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 24<sup>th</sup>, 2009 has been entered.

### ***Claim Rejections - 35 USC § 103***

2. Claims 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shirasaki et al. (USP #5,522,395) in view of Park et al. (US 2002/0183631).

3. As to claim 11, Shirasaki teaches a device for detecting arterial pressure comprising a cuff (1), means for inflating said cuff (2), decompression means (3), memory means (8) to detect and store the sphygmie pulses. The device allows for the identification of pulses (Fig. 8) and inherently provides for intervention of an operator to detect the sphygmie pulses and to make a subjective judgment (by viewing the graph and coming to a conclusion). Shirasaki fails to teach the storage of data in chart form. However, Park teaches a device for detecting the pulse wave of the user and storing the measured pulse wave information (Abs). Since graphs are derived from the pulse wave data by applicant's own admission ([0031]), this would be equivalent to the storage of

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data in chart form. As such, it would have been obvious to one of ordinary skill in the art to modify the arterial pressure measurement device of Shirasaki with the pulse wave storage means taught by Park to enable the user to store the entirety of the measurement data for further analysis.

4. As to claim 12, Shirasaki teaches a decompression means comprising a valve for providing constant and time-controlled decompression (3).

5. As to claim 13, Shirasaki teaches a decompression means comprising a valve for instantaneous discharge of the chamber (3).

6. As to claim 14, Park teaches that the detecting and storing means are connected to data storage means (50).

7. As to claim 15, Park teaches a display adapted to display detected levels of pressure and levels of sphygmie intensity of the pulsations (40).

8. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shirasaki et al. (USP #5,522,395) in view of Park et al. (US 2002/0183631) as applied to claims 11 above, and further in view of Barker (USP #5,201,320).

13. As to claim 16, the combined teaching of Shirasaki and Park do not disclose a button to be pressed by an operator when the operator detects pulses corresponding to systolic or diastolic pressures.

Barker teaches buttons or switches 32 and 34 (col. 4, lines 39-43) for the purpose of marking off the pressure readings of systolic and diastolic pressures.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the arterial pressure measurement device of Shirasaki incorporating the pulse wave storage means taught by Park with the button apparatus taught by Barker in order to simplify operation of the device, to allow the operator to concentrate on determining only the points of systolic or diastolic pressure, without needing to account for the actual pressure readings themselves.

9. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shirasaki et al. (USP #5,522,395) in view of Park et al. (US 2002/0183631) and further in view of Caro et al. (US 2002/0095090).

10. As to claim 17, the combined teachings of Shirasaki and Park disclose the invention substantially as claimed. Shirasaki teaches a method for detecting arterial pressure comprising the steps of pumping air into a cuff (1), decompressing said chamber (col. 1, lines 17-29). Park teaches the storing of a chart of the sphygmic pulses (Abs). The combined teachings of Shirasaki and Park fail to teach the intervention and subjective judgment of an operator using a stethoscope to identify the pulses corresponding to the appearance and disappearance of the pulse beat. However, Caro teaches that a manual measurement could be input in place of an automated sphygmomanometry entry for a calibration signal ([0047]). In addition, Caro teaches that the traditional manual method of measuring blood pressure is with a stethoscope ([0004]). As such, it would have been obvious for one of ordinary skill in the art to modify the arterial pressure measurement device of Shirasaki incorporating the pulse

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wave storage means taught by Park by manual operation of an operator using a stethoscope as taught by Caro in order to allow for an accurate measurement in the event that the automated determination method is obviously in error or malfunctioning in the operator's judgment.

11. As to claim 18, Shirasaki teaches a decompression means comprising a valve for providing constant and time-controlled decompression (3).

12. As to claim 19, Park teaches a device for detecting the pulse wave of the user and storing the measured pulse wave information to allow for subsequent analysis (Abs).

13. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shirasaki et al. (USP #5,522,395), Park et al. (US 2002/0183631), and Caro et al. (US 2002/0095090) as applied to claims 17 above, and further in view of Barker (USP #5,201,320).

14. As to claim 20, the combined teaching of Shirasaki and Park do not disclose a step of pressing on a button at sphygmie pulses corresponding to systolic and diastolic pressure are detected, such that the pressures are "marked" on a digital scale of the device.

Barker teaches buttons or switches 32 and 34 (col. 4, lines 39-43) for the purpose of marking off the pressure readings of systolic and diastolic pressures. In addition, Barker discloses a first unit 31 which contains two displays 28 and 30 which

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display the pressure readings at the systolic and diastolic pressure, thus "marking" the pressures.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the arterial pressure measurement device of Shirasaki incorporating the pulse wave storage means taught by Park and the manual operation of an operator using a stethoscope as taught by Caro with the step of pressing buttons that "mark" the systolic and diastolic pressure points as taught by Barker in order to simplify operation of the device, to allow the operator to concentrate on determining only the points of systolic or diastolic pressure, without needing to account for the actual pressure readings themselves.

15. Claims 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shirasaki et al. (USP #5,522,395) in view of Park et al. (US 2002/0183631) and further in view of Sjonell (USP #5,042,496).

16. As to claim 21, the combined teachings of Shirasaki and Park teach the claim substantially as recited. The combined teachings of Shirasaki and Park fail to teach a cuff provided with a printed scale that indicates, when the cuff is applied to the patient, the circumference of the arm of the patient. Sjonell teaches a cuff with a tape measure mounted on the cuff so as to enable the measurement of arm circumference when placed on the arm in a conventional manner so as to use the arm circumference measurement to correct the blood pressure measurement (col. 2, line 35 to col. 3, line 15). As such, it would have been obvious to one of ordinary skill in the art to modify the

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arterial pressure measurement device of Shirasaki incorporating the pulse wave storage means taught by Park with the cuff incorporating a printed scale similar to that of Sjonell in order to allow measurement of the arm circumference to allow for correction action on the blood pressure measurement.

17. As to claim 22, Shirasaki teaches a decompression means comprising a valve for providing constant and time-controlled decompression (3).

18. As to claim 23, Shirasaki teaches a decompression means comprising a valve for instantaneous discharge of the chamber (3).

19. As to claim 24, Park teaches that the detecting and storing means are connected to data storage means (50).

20. As to claim 25, Park teaches a display adapted to display detected levels of pressure and levels of sphygmie intensity of the pulsations (40).

21. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shirasaki et al. (USP #5,522,395), Park et al. (US 2002/0183631), and Sjonell (USP #5,042,496) as applied to claim 21 above, and further in view of Barker (USP #5,201,320).

13. As to claim 26, the combined teaching of Shirasaki, Park, and Sjonell do not disclose a button to be pressed by an operator when the operator detects pulses corresponding to systolic or diastolic pressures.

Barker teaches buttons or switches 32 and 34 (col. 4, lines 39-43) for the purpose of marking off the pressure readings of systolic and diastolic pressures.



It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the arterial pressure measurement device of Shirasaki incorporating the pulse wave storage means taught by Park and the cuff incorporating a printed scale taught by Sjonell with the button apparatus taught by Barker in order to simplify operation of the device, to allow the operator to concentrate on determining only the points of systolic or diastolic pressure, without needing to account for the actual pressure readings themselves.

22. Claims 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shirasaki et al. (USP #5,522,395) and Park et al. (US 2002/0183631) and further in view of Caro et al. (US 2002/0095090) and Sjonell (USP #5,042,496).

23. As to claim 27, the combined teachings of Shirasaki and Park disclose the invention substantially as claimed. Shirasaki teaches a method for detecting arterial pressure comprising the steps of pumping air into a cuff (1), decompressing said chamber (col. 1, lines 17-29). Park teaches the storing of a chart of the sphygmic pulses (Abs). The combined teachings of Shirasaki and Park fail to teach the intervention and subjective judgment of an operator using a stethoscope to identify the pulses corresponding to the appearance and disappearance of the pulse beat.

However, Caro teaches that a manual measurement could be input in place of an automated sphygmomanometry entry for a calibration signal ([0047]). In addition, Caro teaches that the traditional manual method of measuring blood pressure is with a stethoscope ([0004]). As such, it would have been obvious for one of ordinary skill in the

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art to modify the arterial pressure measurement device of Shirasaki incorporating the pulse wave storage means taught by Park by manual operation of an operator using a stethoscope as taught by Caro in order to allow for an accurate measurement in the event that the automated determination method is obviously in error or malfunctioning in the operator's judgment. The combined teachings of Shirasaki, Park, and Caro fail to teach the use of a value of the circumference of the arm by reading a scale printed on the cuff and using the value as a corrective factor for the arterial pressure measurement.

Sjonell teaches a cuff with a tape measure mounted on the cuff so as to enable the measurement of arm circumference when placed on the arm in a conventional manner so as to use the arm circumference measurement to correct the blood pressure measurement (col. 2, line 35 to col. 3, line 15). As such, it would have been obvious to one of ordinary skill in the art to modify the arterial pressure measurement device of Shirasaki incorporating the pulse wave storage means taught by Park and the use of a manual operation taught by Caro with the cuff incorporating a printed scale similar to that of Sjonell in order to allow measurement of the arm circumference to allow for correction action on the blood pressure measurement.

24. As to claim 28, Shirasaki teaches a decompression means comprising a valve for providing constant and time-controlled decompression (3).

25. As to claim 29, Park teaches a device for detecting the pulse wave of the user and storing the measured pulse wave information to allow for subsequent analysis (Abs).

26. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shirasaki et al. (USP #5,522,395), Park et al. (US 2002/0183631), Caro et al. (US 2002/0095090) and Sjonell (USP #5,042,496), as applied to claim 27 above, and further in view of Barker (USP #5,201,320).

27. As to claim 30, the combined teaching of Shirasaki, Park, Caro, and Sjonell do not disclose a step of pressing on a button at sphygmie pulses corresponding to systolic and diastolic pressure are detected, such that the pressures are "marked" on a digital scale of the device.

Barker teaches buttons or switches 32 and 34 (col. 4, lines 39-43) for the purpose of marking off the pressure readings of systolic and diastolic pressures. In addition, Barker discloses a first unit 31 which contains two displays 28 and 30 which display the pressure readings at the systolic and diastolic pressure, thus "marking" the pressures.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the arterial pressure measurement device of Shirasaki incorporating the pulse wave storage means taught by Park, the manual operation taught by Caro, and the use of the arm circumference as a corrective factor as taught by Sjonell with the step of pressing buttons that "mark" the systolic and diastolic pressure points as taught by Barker in order to simplify operation of the device, to allow the operator to concentrate on determining only the points of systolic or diastolic pressure, without needing to account for the actual pressure readings themselves.

***Response to Arguments***

28. Applicant's arguments with respect to claims 11-20 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTIAN Y. JANG whose telephone number is (571)270-3820. The examiner can normally be reached on Mon. - Fri. (8AM-5PM) EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 3735

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Examiner, Art Unit 3735  
6/2/09